AMENDED IN SENATE MAY 24, 2004
AMENDED IN SENATE APRIL 19, 2004
AMENDED IN SENATE APRIL 1, 2004
AMENDED IN SENATE MARCH 16, 2004
AMENDED IN SENATE MARCH 1, 2004

SENATE BILL

No. 1149

Introduced by Senator Ortiz (Coauthor: Senator Murray)

January 26, 2004

An act to add Section 4001.4 to, and to add and repeal Sections 4001.2 and 4001.3 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1149, as amended, Ortiz. Dangerous drugs: Canadian pharmacies: foreign suppliers.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy and makes it responsible for licensing and regulating pharmacy practices, including the furnishing of dangerous drugs, as defined.

This bill would require the board to develop and disseminate information identifying pharmacies in Canada that meet recognized standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs to California residents. The bill would require each pharmacy located in Canada that seeks to be identified for these purposes to pay the board an annual fee of \$1,500. The bill would also

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require the board to collect, publish, and post on an Internet Web site information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have violated safe shipment, handling, and processing standards. The bill would repeal its these provisions on January 1, 2008.

The bill would require the board to determine the workload and resource requirements to implement these provisions. The bill would create the Access to Affordable Prescription Drugs Fund where fees and voluntary contributions to support those activities would be deposited. The bill would make this revenue available to the board for expenditure for those purposes upon appropriation by the Legislature in the annual Budget Act.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds all of the following:

- (a) Prescription medications are an essential part of health care delivery and have contributed to increasing the life expectancy of patients and treating their diseases and conditions.
- (b) Despite this, due to the high cost of prescription medications, many Californians, especially elderly, disabled, and low-income persons, face difficulty accessing the medications they need to maintain their health.
- (c) As one means of accessing affordable prescription medications, increasing numbers of Californians are purchasing prescription medications from foreign countries, in many cases through an Internet Web site.
- (d) California consumers currently have few ways of determining which outlets and suppliers of prescription medications in foreign countries are safe and reliable, particularly those offering their products through an Internet Web site.
- (e) Canadian pharmacies that are licensed by the provinces in which they are located generally meet safety standards for the acquisition, distribution, and dispensing of prescription medications that are as stringent as those in California.
- (f) In order to help ensure access to prescription medications, there is a need to provide consumers with information about safe and reliable Canadian pharmacies and about fraudulent and unsafe

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suppliers or outlets of prescription medications whose practices may potentially harm consumers, and there is a need to assist consumers in making informed choices for obtaining prescription medications for their health care needs.

SEC. 2. Section 4001.2 is added to the Business and Professions Code, to read:

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- 4001.2. (a) The board shall develop and disseminate information identifying Canadian pharmacies that have established that they meet recognized standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs to persons in California. As part of this requirement, the board shall establish an interactive Internet Web site that links consumers to, or provides information about, Canadian pharmacies that the board has determined meet recognized standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs to persons in California.
- (b) For the purposes of this section, a Canadian pharmacy that 18 meets recognized standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs means a pharmacy that is located in Canada and meets all of the following requirements:
 - (1) Is licensed as a pharmacy by the province in which it is located and its license is not revoked, suspended, or subject to other disciplinary action.
 - (2) Notifies the board within three business days of any change in its licensure status and any pending disciplinary action against
 - (3) Is accredited or eligible for accreditation by the Internet and Mail Order Pharmacy Accreditation Commission or is a member of the Canadian International Pharmacy Association.
 - (4) Meets the requirements for licensure by the board as a pharmacy.
 - (5) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.
 - (6) Requires a valid prescription from a physician and surgeon licensed to practice in the United States before selling the prescribed drug.
- 38 (7) Maintains a service department to respond to all consumer inquiries.

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 (8) Discloses, on its Internet Web site and in packaging accompanying any shipped drugs, that the consumer may file a complaint regarding the pharmacy with the relevant Canadian provincial licensing authority and with the pharmacy, and provides the contact information for filing the complaint.

- (9) Does not furnish any of the following types of drugs:
- (A) Narcotics and other controlled substances.
- (B) Drugs for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.
- (C) Drugs that are not approved by the Canadian Therapeutic Products Directorate for sale in Canada.
- (D) Drugs that require refrigeration or that cannot be safely shipped by mail.
- (10) Ensures that all physicians and surgeons, pharmacists, and technicians in its employ are properly licensed according to Canadian laws and their licenses are not revoked, suspended, or subject to other disciplinary action.
- (11) Complies with all personal health and medical information privacy laws applicable to a pharmacy located in California.
- (12) Does not exceed the prescribed amount and does not exceed a three-month supply of the prescribed drug.
- (13) Complies with all Canadian laws applicable to furnishing drugs.
- (14) Does not furnish a drug if the consumer indicates he or she has not previously taken that drug.
- (15) Does not repackage the drug from the original packaging by the drug manufacturer unless required to dispense the prescription or to package the drug at the consumer's request in a childproof container.
- (c) The board shall discontinue providing information to consumers and providing Internet Web site links to a pharmacy that the board determines does not meet the requirements of this section.
- (d) Each pharmacy located in Canada that seeks to be identified by the board pursuant to this section shall pay the board an annual fee of one thousand five hundred dollars (\$1,500). The fees shall be deposited into the Access to Affordable Prescription Drugs Fund created by Section 4001.4.

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(e) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date. SEC. 3. Section 4001.3 is added to the Business and

5 Professions Code, to read:

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- 4001.3. (a) The board shall collect, publish, and post on an Internet Web site created pursuant to Section 4001.2, information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have been found to have violated recognized standards for the safe shipment, handling, and processing of dangerous drugs.
- (b) In carrying out this section, the board may rely on information made available by regulatory and law enforcement bodies, including, but not limited to, the federal Food and Drug Administration, the United States Customs Service, prescription drug regulatory bodies of foreign countries, the Attorney General, the United States Department of Justice, the boards of pharmacy of other states, and the National Association of Boards of Pharmacy.
- (c) The board is not required to conduct surveillance activities or its own investigations in order to carry out the requirements of this section, but is authorized to engage in those activities to the extent its resources permit.
- (d) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.
- SEC. 4. Section 4001.4 is added to the Business and Professions Code, to read:
- 4001.4. (a) The board shall determine its annual workload and resource requirements to implement Sections 4001.2 and 4001.3, including through a request for proposal process to determine the number of pharmacies that are interested in being identified and having their information provided to California consumers.
- (b) The board may receive voluntary contributions to support 36 its activities pursuant to Sections 4001.2 and 4001.3. The contributions shall be deposited into the Access to Affordable Prescription Drugs Fund which is hereby created in the State Treasury. The revenue in the fund shall be made available to the board for expenditure solely for the purpose of supporting the

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- 1 board's activities pursuant to Sections 4001.2 and 4001.3 upon
- 2 appropriation by the Legislature in the annual Budget Act.
- 3 (c) The board may contract for any resources needed to 4 implement Sections 4001.2 and 4001.4.